Lyra Therapeutics Reports Second Quarter 2021 Financial Results and Highlights Recent Accomplishments

August 9, 2021

- Successful EOP2 FDA meeting for LYR-210 in CRS; Phase 3 program on track to begin around year-end 2021 -

- Licensing agreement with LianBio for LYR-210 in Greater China and other Asian markets -

- Positive topline results of LYR-210 PK study support 505(b)(2) NDA pathway -

WATERTOWN, Mass., Aug. 09, 2021 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, and local delivery of medications to the ear, nose and throat (ENT) passages and other diseased tissues, today reported financial results for the quarter ended June 30, 2021, and highlighted recent accomplishments.

Recent Company Highlights

- In June, Lyra announced the positive outcome of its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) for LYR-210 for the Treatment of Chronic Rhinosinusitis (CRS). Lyra and the FDA established key elements of the Phase 3 program to support a 505(b)(2) new drug application, including the single primary endpoint, which will evaluate improvement at week 24 using a composite score of three cardinal symptoms of CRS.
- Lyra announced a strategic partnership and exclusive license agreement with LianBio to develop and commercialize LYR-210 in Greater China and other Asian markets. Lyra received an upfront payment of $12 million and is eligible to receive up to $135 million in future payments based upon development, regulatory and commercialization milestones, as well as low double-digit royalties on net sales of LYR-210 in the licensed territories.
- The Company announced positive topline results of a pharmacokinetic (PK) study of LYR-210 in patients with CRS. The data were supportive of LYR-210's safety profile and provide a PK bridge to the established safety of mometasone furoate for a 505(b)(2) pathway for New Drug Approval (NDA) submission.

"Following our successful End-of-Phase 2 meeting with the FDA, we believe that we have a clear path forward to advance LYR-210 into Phase 3 clinical development for the treatment of Chronic Rhinosinusitis, which we expect to begin around year-end," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. "Our second CRS product, LYR-220 for post-surgical CRS patients, is also advancing and remains on track to enter Phase 2 later this year. We believe LYR-210 and LYR-220 will disrupt the current CRS treatment landscape by providing a new pharmacologic solution for the full spectrum of the 4 million U.S. CRS patients who fail medical management each year."

Second Quarter 2021 Financial Highlights

- Cash and cash equivalents as of June 30, 2021 were $69.0 million, compared with $74.6 million at December 31, 2020. The Company expects its cash balance to be sufficient to fund its planned operations into 2023.
- Research and development expenses for the quarter ended June 30, 2021 were $7.5 million compared to $2.1 million for the same period in 2020.
- General and administrative expenses for the second quarter 2021 were $3.6 million compared to $2.4 million for the same period in 2020.
- Total operating expenses for the quarter ended June 30, 2021 were $11.1 million compared to $4.5 million for the same period in 2020.
- Net loss for the second quarter was $11.0 million compared to $4.5 million for the same period in 2020.

Conference Call and Webcast Details

LYRA will host a conference call and live webcast today at 4:30 p.m. ET. To access the live call by phone, dial (833) 519-1249 (domestic) or (914) 800-3822 (international) and use the conference ID: 6997916. To access the live webcast of the call, please visit the Investor Relations section of the Lyra Therapeutics website at https://investors.lyratherapeutics.com/. The recorded webcast will be available for replay for approximately 30 days following the call.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, local delivery of medications to diseased tissues not accessible with conventional therapeutic approaches. Lyra's XTreo™ platform is comprised of a biocompatible mesh scaffold, an engineered elastomeric matrix and a versatile polymer-drug complex. The company's current pipeline of therapeutics target tissues deep in the ear, nose and throat passages and are designed to deliver continuous drug therapy for months following a single non-invasive, in-office administration. Lyra's lead product candidate, LYR-210, is in late-stage clinical development for the treatment of chronic rhinosinusitis and is designed

to deliver up to six months of continuous anti-inflammatory drug therapy to the sinonasal passages. For more information, please visit www.lyratherapeutics.com and follow us on LinkedIn and Twitter.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the company's clinical advancement of LYR-210 for the treatment of CRS and our expectations regarding the development and commercialization of LYR-210 pursuant to the terms of the LianBio License Agreement. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the fact that the company has incurred significant losses since inception and expects to incur losses for the foreseeable future; the company's need for additional funding, which may not be available; the company's limited operating history; the fact that the company has no approved products; the fact that the company's product candidates are in various stages of development; our the fact that the company may not be successful in its efforts to identify and successfully commercialize its product candidates; the fact that clinical trials required for the company's product candidates are expensive and time-consuming, and their outcome is uncertain; the fact that the FDA may not conclude that certain of the company's product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway; the company's inability to obtain required regulatory approvals; effects of recently enacted and future legislation; the possibility of system failures or security breaches; effects of significant competition; the fact that the successful commercialization of the company's product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies; failure to achieve market acceptance; product liability lawsuits; the fact that the company relies on third parties for the manufacture of materials for its research programs, pre-clinical studies and clinical trials; the company's reliance on third parties to conduct its preclinical studies and clinical trials; the company's inability to succeed in establishing and maintaining collaborative relationships; the company's reliance on certain suppliers critical to its production; failure to obtain and maintain or adequately protect the company's intellectual property rights; failure to retain key personnel or to recruit qualified personnel; difficulties in managing the company's growth; effects of natural disasters; the fact that the global pandemic caused by COVID-19 could adversely impact the company's business and operations, including the company's clinical trials; the fact that the price of the company's common stock may be volatile and fluctuate substantially; significant costs and required management time as a result of operating as a public company and any securities class action litigation. These and other important factors discussed under the caption "Risk Factors" in the company's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2021 and its other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

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LYRA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 7,505	$ 2,103	$ 12,275	$ 5,067
General and administrative	3,560	2,442	6,621	3,726
Total operating expenses	11,065	4,545	18,896	8,793
Loss from operations	(11,065)	(4,545)	(18,896)	(8,793)
Other income:				
Interest income	26	5	55	21
Total other income	26	5	55	21
Net loss	$ (11,039)	$ (4,540)	$ (18,841)	$ (8,772)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.56)	$ (1.45)	$ (2.11)
Weighted-average common shares outstanding—basic and diluted	12,991,837	8,182,725	12,968,820	4,206,793

LYRA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 69,046	$ 74,593
Prepaid expenses and other current assets	1,027	1,324
Total current assets	70,073	75,917
Property and equipment, net	3,853	2,165
Operating lease right-of-use assets	1,834	2,301
Restricted cash	329	329
Other assets	243	118
Total assets	$ 76,332	$ 80,830
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,899	$ 922
Accrued expenses and other current liabilities	2,976	2,977
Operating lease liabilities	1,029	985
Total current liabilities	5,904	4,884
Operating lease liabilities, net of current portion	929	1,454
Deferred revenue	12,000	—
Total liabilities	18,833	6,338
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 13,001,105 and 12,932,377 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	226,211	224,363
Accumulated deficit	(168,725)	(149,884)
Total stockholders' equity	57,499	74,492
Total liabilities and stockholders' equity	$ 76,332	$ 80,830

Source: Lyra Therapeutics